

Practitioner's Docket No. 399037

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Jordan et al.)

Application No.: 09/021,421)

Group No.: 1614

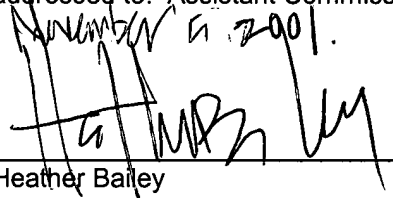
Filed: February 10, 1998)

Examiner: Goldberg, J.

For: CHELATED 8-HYDROXYQUINOLINE)
AND USE THEREOF IN A METHOD OF)
TREATING EPITHELIAL LESIONS)

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail bearing label number EL 820326935 with sufficient postage in an envelope addressed to: Assistant Commissioner for Patents and Trademarks, Washington, DC 20231, on

November 5, 2001.

Heather Bailey

ASSISTANT COMMISSIONER FOR
PATENTS
WASHINGTON, D.C. 20231

Sir:

DECLARATION OF RUSSELL T. JORDAN UNDER RULE 1.132

1. I am Russell T. Jordan, and I am named as an inventor in the above-identified patent application. My employment status is that I am presently retired, though I am assisting Dermex Pharmaceuticals with the patenting of chelated forms of oxyquinoline for use in treating cancers.

2. My career has spanned several decades during which I actively performed bench research investigating prospective pharmaceuticals. A copy of my curriculum vitae is attached as Exhibit A.

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3. I have reviewed the office action that the Examiner mailed to our attorney on May 3, 2001. The office action rejects claims 1-7, 14-22 and 34-37 under 35 U.S.C. as being unpatentable over WO 88/03805.

4. WO 88/03805 lists me as an inventor, and my current address is the same as it was in 1988, namely, 1809 Indian Meadows Lane, Fort Collins, Colorado 80525.

5. I was one of the principal researchers who developed the subject matter disclosed in WO 88/03805, and I am familiar with the materials and methods that were used and described therein.

6. Page 2 of the Office Action dated May 3, 2001 relies upon the disclosed use of quercetin on page 119, line 23 being mixed with halide of zinc for "prevention of tumor cells." A passage on page 9 is relied upon for the recitation of escharotics including zinc chloride. Page 10 is recited for the recitation of carriers, and page 34 is recited for the utility including cancerous tumors. Page 35 is relied upon for the recitation that the zinc content can range from 1% to 30% and the ratio of catechol to zinc can range from 1:5 to 5:1.

7. WO 88/03805 does not disclose the use of 8-hydroxyquinoline.

8. Exhibit B contains photostatic copies of certain pages from the Merck Index (11th edition). Abstract 8044 shows the structure of quercetin, which is generally related to the bioflavonoid family of compounds that was the subject of WO 88/03805. This material is produced in nature and may be purified from the rinds, barks, clover blossoms, and ragweed pollen.

9. Abstract 4778 of Exhibit B shows the structure of 8-hydroxyquinoline, as disclosed and claimed in the present application. This structure is very different from that of quercetin and must be synthesized according to a variety of procedures, such as reacting 0-aminophenol, glycerol and H_2SO_4 . The 8-hydroxyquinoline molecule differs from pure quercetin in many ways including the loss of an aromatic ring, a single hydroxyl group located where none exist in quercetin, and having an oxygen-containing ring, as opposed to a nitrogen-containing ring.

10. During my long years of research, I have often observed that chemicals which are sold to researchers are not necessarily as pure as they are supposed to be, and I have implemented quality control procedures including chemical and spectroscopic analysis to assure the purity of chemicals being used in my research. Raw quercetin in the form of a semi-purified herbal extract may be contaminated with a variety of materials. I have sometimes observed contamination with what may be 8-hydroxyquinoline, though I cannot attest to the source or the reason for such contamination and it may have happened in my lab. Accordingly, during the research that produced the subject matter of WO 88/03805, sufficient quality control procedures were in place to assure that only pure forms of quercetin were used in our tests. Thus, WO 88/03805 does not teach the use of 8-hydroxyquinoline and such use did not occur by accident.

11. The results that are produced by zinc-bonded forms of quercetin and 8-hydroxyquinoline are very different in kind. The quercetin compositions described in WO 88/03805 are primarily useful as tumor control agents. They sometimes result in eradication of the lesion, but the presently claimed compositions work much

better by completely eradicating a wide variety of lesions. Thus, the presently claimed 8-hydroxyquinoline-based materials are curative therapeutics, as opposed to tumor or lesion control agents.

12. The former recitation in claim 22 of using quercetin as a source of 8-hydroxyquinoline was an error that resulted from a miscommunication, and I have instructed our attorney to cancel this claim.

13. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date: 7/12/01

By: Russell T. Jordan

Russell T. Jordan